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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/813,820

03/22/2001

Magnus Hook

P06357US02/BAS

8424

881 7590 08/11/2004

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/11/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/813,820

Applicant(s)

HOOK ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### FINAL ACTION

1. This Office Action is responsive to Applicant's response filed September 12, 2002. Applicant's Declarations filed under 37 C.F.R. 1.131 of Dr. Hook and Dr. House-Pompeo filed September 12, 2002 are acknowledged. Applicant's Declarations filed under 37 C.F.R. 1.131 and 1.132 of Dr. Patti filed September 12, 2002 are acknowledged.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

3. For clarification of the record the rejection under claims 1-3, 5-13 and 14-15 as anticipated by Patti et al (*The Journal of Biological Chemistry*, Vol. 270, No. 20, May 19, 1995) was cited as being a reference under 35 U.S.C. 102(b), this is a typographical error. The reference should have been applied under 35 U.S.C. 102(a). The Office apologizes for the oversight. Applicant's Declaration filed under 37 C.F.R. 1.131 is sufficient to overcome this rejection.

***Objection/Rejections Withdrawn***

4. In view of Applicant's response the following rejections are withdrawn.
- a) objection to the specification, page 2, paragraph 2.
  - b) Rejection of claims 1-3, 5-11 and 13-16 under 35 U. S.C.102(b), pages 2-3, paragraph 3 of the previous Office action.
  - c) Rejection of claims 1-3, 5-11 and 13-16 under 35 U. S.C.102(b), pages 3-4, paragraph 4 of the previous Office action.
  - d) Rejection of claims 1-3 and 5-16 under 35 U. S.C.102(b), pages 3-4, paragraph 4 of the previous Office action.

***Rejections Maintained***

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 1-16 for the reasons set forth on page 5 paragraph 6 of the previous Office Action.

The rejection was on the grounds that the Patti et al teach monospecific antibodies that recognized a recombinant *Staphylococcus aureus* collagen adhesin (see the Abstract and page 4771, 2<sup>nd</sup> column). Limitations such as "suitable for parental, oral, intranasal, subcutaneous or intravenous administration" and "prevents *S. aureus* infection" are being view as limitations of intended use.

Since the Office does not have the facilities for examining and comparing applicant's antibody with the antibody of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the antibody of the prior art does not possess the same material structural and functional characteristics of the claimed antibody). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claimed invention differs from that of the prior art because the prior art reference discloses the generation of antibodies to the

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whole *cna* protein and not specific subregions as disclosed by the claimed invention and the instant specification. Applicant refers to the Declaration submitted by Dr. Patti that teaches that antibodies raised against specific subregions of the collagen binding domain will have different and distinct properties as compared to antibodies raised to the entire protein. Applicant urges that in fact antibodies may be generated against the entire protein, however, this does not disclose or suggest a protein generated against a specific region of the whole protein.

Applicant's arguments filed September 12, 2002 have been fully considered but they are not persuasive. The claims are directed to an isolated antibody which binds to a purified peptide composition consisting essentially of the amino acid of SEQ ID NO:4 wherein said antibody prevents *S. aureus* infection. The claims are not limited to antibodies that are specific to subregions of the collagen binding domain. There is no requirement or limitation in the claims that the antibodies are specific subregions of the collagen binding domain. Therefore, Applicant is arguing limitations that are not recited in the claims. It should be noted that the claims recite "consisting essentially of" which is open claim language which suggest that other components <sup>may be present</sup> that do not cause a negative effect on the claimed preparation. Applicant has provided no side-by-side comparison to show that the claimed antibodies differ from that of the prior art. It is the Examiner's position that the claimed antibodies are the same as the antibodies of the prior art. Therefore, Patti et al anticipate the claimed invention.

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***Status of Claims***

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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**Conclusion**

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

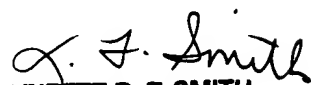
Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Vanessa L. Ford  
Biotechnology Patent Examiner  
July 27, 2004

  
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